IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Marc Howard Spinoza	Group Art Unit: 3763
Serial No.: 09/506,361	Examiner: VU, Quynh-Nhu Hoang
Filed: February 18, 2000	Atty. Dkt. No.: FIFW:019US
For: A METHOD OF SECURING A LINE TO A PATIENT, FASTENERS AND THEIR USE TO SECURE A LINE TO A PATIENT	

DECLARATION OF MARC HOWARD SPINOZA UNDER 37 C.F.R. § 1.132

I, Marc Howard Spinoza, declare that:

1. I am the inventor of the above-captioned patent application and have a financial interest in its issuance.

2. I am the Senior Clinical Lead of the International Patients Unit at Great Ormond Street Hospital for Children NHS Trust, London WC3JH. I am a Medical Practitioner qualifying in 1994. My specialist training and practice has included adult cardiology, general medicine, surgery and orthopaedics. I have worked in both neonatal and paediatric intensive care. I have also worked in emergency medicine both adult and paediatric areas. I have worked at Great Ormond Street Hospital since 2000 and covered a wide variety of medical specialties including oncology, gastroenterology, respiratory, immunology, orthopaedics, general surgery, renal, endocrine and neurology.

3. I have invented an improved medical or surgical fastener for securing a tube to a patient, which is currently claimed in the above-captioned patent application.

4. My invention has, and is, enjoying commercial and technical success as described in more detail below.

5. My invention, as reviewed by all of the individuals, companies and official bodies mentioned below incorporated all of the features set forth in Claim 81. In particular my invention as reviewed comprised "A medical or surgical fastener…comprising a sterile tubular sleeve", which specific features enable the fastener to be used in a medical setting. Further, those mentioned below were aware that "the sterile tubular sleeve exerts a pressure distributed over an elongate portion of the tube", providing particular advantages to a medical fastener, as specifically mentioned in the Declaration of Professor Lewis Spitz (Appendix A). The features set out above are distinguishing features of pending Claim 81.

6. My invention as reviewed by all of the individuals, companies and official bodies mentioned below incorporated all of the features set forth in Claim 95. In particular, in addition to the features set out in Paragraph 5 above, my invention included "a ring at at least one end of the sleeve", as claimed in pending Claim 95. In some embodiments, the ring was formed integrally with the sleeve. The ring adds a further distinguishing feature to Claim 95.

7. My invention has received awards in the industry. For example, my invention has received an award from a European Union-backed Business Innovation Centre. The award was based on factors including the innovative nature and commercial potential of my invention. My invention has also received an Innovation Award from Medical Futures, a UK team of clinicians and business experts who promote innovation in medical fields.

8. My invention has and is experiencing commercial success. A wide range of medial experts, government departments and multinational corporations have shown interest in the invention, examples of which are set out below:

- Parliamentary Under Secretary of State Professor the Lord Darzi of Denham KBE at the UK Government Department of Health and Under-Secretary of State for Defence and Minister for Veterans Derek Twigg MP at the UK Government Ministry of Defence have both expressed support for widespread adoption of the invention in civil and military medical situations.
- My invention is currently undergoing the accreditation process for use by NATO, which will enable medical practitioners in the field to provide hygienic, fast and secure deployment of medical lines.
- My invention is being studied and reviewed by a number of companies, including a large multinational corporation operating primarily out of the United States of America, with a recent market capitalization of more than $200 million, and a further multinational corporation, based in Europe, which has been operating in the field of Healthcare Technology for more than 25 years and we are currently in negotiations to commence large scale manufacture and distribution of the invention.
- My invention has been demonstrated and trialed extensively in a range of medical fields, as described in more detail below, and we have received significant expressions of interest from medical practitioners and purchasing departments regarding the purchase of products incorporating my invention.

9. We have a contract with a long-established international distribution company, who has supplied products incorporating my invention internationally. We are also in late-stage negotiations with a further international medical distributor, who wish to agree a contract to enable them to distribute products incorporating my invention.

10. My invention has and is experiencing technical success. Major teaching and research hospitals and university departments both in the United Kingdom and the United States of America have reviewed and assessed the invention. My invention has been reviewed and trialed in a number of hospitals in the UK, including:

- Great Ormond Street Hospital for Children, London, UK
- Homerton University Hospital, London, UK
- Guy's Hospital, London, UK
- Hillingdon Hospital London, UK
- Addenbrookes Hospital, Cambridge, UK

Statements from Mr Ian Chilcott at the Hillingdon Hospital (Appendix B), Dr Anna Curley at Addenbrookes Hospital (Appendix C) and Professor Lewis Spitz at Great Ormond Street Hospital (Appendix A) are attached confirming that the invention was found to be successful, efficient and easy to use.

The invention has also been demonstrated at The Queens Veterinary School Hospital, University of Cambridge, UK and it was considered that the invention would provide great benefits in veterinary work, as evidenced by the attached letter from Dr Nicola Holdstock, European Specialist in Equine Internal Medicine (Appendix D).

11. My invention received funding from the Institute of Child Health, the leading British academic research institution for child health, to fund a trial in the cardiothoracic unit at Great Ormond Street Hospital for Children. The trial involved 50 patients and around 12 medical practitioners, with hundreds of devices incorporating my invention being deployed over a period of around 4 months.

12. My invention is currently being reviewed for clearance by the United States Government Department of Health and Human Services Food and Drug Administration. An initial response from the FDA, a copy of which is submitted herewith as Appendix E, indicates that my invention "introduces a different fundamental scientific technology to an Intravascular catheter securement device" and that the department has "not previously seen the....technological features in an Intravascular securement device".

13. In my work, I regularly encounter situations in which the invention could reduce medical complications for patients, save time and money for medical practitioners and, as a result, save the lives of patients. My invention can act to simplify the implementation and management of medical lines and tubes, such as drains, in a wide range of medical and surgical fields, including neonatal, obstetrics, gynecology, ear nose and throat, plastic surgery and cardiothoracic surgery.

14. My invention has received favorable press coverage in important, highly-distributed newspapers. For example, an article describing the invention that is the subject of the present application was published in April 2008 in the London Evening Standard Newspaper, which has an average daily circulation of more than 280,000 copies.

15. I declare that all statements made of my own knowledge are true and all statements made on information are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued on it.

Date: 24.4.09.

Marc Howard Spinoza

APPENDIX A

Professor Lewis Spitz

MBChB, PhD, MD(Hon), FRSC(Edin), FRCS(Eng), FRCS(I)Hon, FAAP(Hon), FRCPCH, FCS(SA)Hon.

Emeritus Nuffield Professor of Paediatric Surgery
Consultant Paediatric Surgeon

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e-mail: lspitz@ich.ucl.ac.uk

1/12/05

1 IDENTIFICATION OF DECLARANT:

2.QUALIFICATIONS:

3 VIEW OF SPINOZA UNIVERSAL LINE LOCK (SULL)

Dr Spinoza has demonstrated the device and provided me with some literature

The SULL appears to be a simple and effective device, which in my opinion will have many applications, most certainly in my field of surgery.

The SULL provides a versatile solution to the attachment, securement, adjustment, removal and review of medical lines and particularly involves a minimum of trauma evident in current securement practices.

The ability to see exactly what is happening at the wound site and the working effectiveness of medical tubing in either drainage or drug delivery is unique.

4. APPLICATION:

The device offers a much simpler securement, adjustment, removal and review methodology widening the field of expertise required for such procedures

Tubing is protected at all times by the forces spread by the device without any sign of collapse or distortion.
The device is quick to apply and extremely straightforward to adjust, and by its use reduce the need for excessive dressing at the wound site, this may reduce the likelihood of infection accordingly.

Displacement of drains or drug delivery systems or medical tubing in any scenario can be and is hazardous, an easy to use adjustable device which provides immense security for medical lines will, in my opinion, save lives.

There are many circumstances in medicine where lines are required, to use a simple small device over a wide range of diameters will, I believe, be accepted as standard practice in the future and will be of enormous value to medical practitioners and patients alike

Professor Lewis Spitz

Chris Watson

APPENDIX B

From: Marc Spinoza [SpinoM@gosh.nhs.uk]
Sent: 05 February 2007 08:40
To: cjwatson@onetel.com
Subject: Fwd: Re: Spinoza Device: Piece for website

for brochure

Header.dat

Dear Chris,

Here it is.

Marc.

>>> "Ian Chilcott" <ichilcott@doctors.org.uk> 04/02/2007 13:57 >>>

> The Spinoza Line Lock is a great innovation in line securement. I am now using this routinely in my gynaecological practice, for securing pelvic drains following open and minimal access pelvic surgery. I have yet to see a problem with the use of this device which is easy to use and secures drains much more efficiently than other methods.

Mr Ian Chilcott
Consultant Gynaecologist
The Hillingdon Hospital
Uxbridge
Middx.
>
>

APPENDIX C

Addenbrooke's Hospital NHS
Cambridge University Hospitals NHS Foundation Trust

NEONATAL INTENSIVE CARE UNIT
Box 226
Direct Line to unit 01223 217678/245853
Fax: 01223 217064
Email: susan.scarrow@addenbrookes.nhs.uk

Addenbrooke's Hospital
Hills Road
Cambridge CB2 2QQ

Switchboard: 01223 245151
www.addenbrookes.org.uk

Dr J S Ahluwalia, Consultant Neonatologist (Sec – 01223 217677)
Dr A Curley, Consultant Neonatologist (Sec – 01223 586629)
Dr A D'Amore, Consultant Neonatologist (Sec – 01223 586829)
Dr K Farrer, Consultant Neonatologist (Sec – 01223 256084)
Dr W Kelsall, Consultant Neonatologist (Sec – 01223 216240)
Dr E Murdoch, Consultant Neonatologist (Sec – 01223 216240)
Dr A Ogilvy-Stuart, Consultant Neonatologist (Sec – 01223 217677)
Dr N Yeaney, Locum Consultant Neonatologist (Sec – 01223 586629)

Our Ref: AEC/ss
Email: susan.scarrow@addenbrookes.nhs.uk

29 August 2007

Mr Chris Watson
Managing Director
Chatham House
Bowling Green Close
Putney.
SW15 3TE

Dear Mr Watson

Thank you very much for sending us samples of your inline locking device for umbilical lines. So far we have found these locking devices successful in maintaining our umbilical venous and umbilical arterial lines in situ. We look forward to receiving the additional batch of locking devices for the smaller umbilical lines. If these go as well as the previous fixators we will be considering ordering these as a routine locking device for umbilical lines. In the case of this happening our equipment manager will send you a request for what lines we need.

Yours sincerely

Dr Anna Curley
Consultant Neonatologist

APPENDIX D

The Queen's Veterinary School Hospital
University of Cambridge
Madingley Road Cambridge CB3 0ES

Tel: 01223 330845 Mob: 07765 222000 Fax: 01223 333860 Email: nbh10@cam.ac.uk

Dr Nicola Holdstock
MA., Vet.MB., Cert.EM.(Stud Med), LVI., ILTM., PhD., Dipl.ECEIM., MRCVS
European Specialist in Equine Internal Medicine & RCVS Specialist in Equine Stud Medicine

24th January 2006

Ref: The SULL

To whom it may concern:

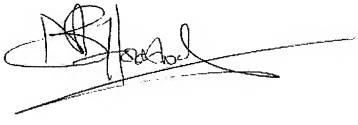
Dr Spinoza presented the SULL device to my colleagues and I at the Equine Hospital, University of Cambridge. The SULL provides a method of securement for many tubing systems which are used in critical care and therefore ensures a simple safe attachment and removal technique. The device is already in clinical use in human medicine and is rapidly replacing conventional methods of securement in a wide variety of tubing systems. I believe the use of the SULL device would also greatly benefit our patients.

Our requirements here at the Veterinary Hospital extends the range of sizes of SULL required because we are dealing with large animals e.g. horses, cattle and lamas, as well as companion animals e.g. dogs, cats and rabbits. Our team has provided Dr Spinoza with a long list of catheter tubes which we feel would all greatly benefit with the addition of a SULL.

We are very keen to introduce the SULL system as soon as possible and Dr Spinoza has asked for this letter of support to speed up the process of production.

If you require any further information please do not hesitate to contact me.

Yours sincerely



APPENDIX E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SULL Ltd.
c/o Cynthia J.M. Nolte, Ph.D., RAC
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 1 3 2007

Re: K063205
Device Name: Spinoza Universal Line Lock
Dated: December 8, 2006
Received: December 13, 2006

Dear Dr. Nolte:

We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Spinoza Universal Line Lock. Based on the information provided in your submission, we believe the Spinoza Universal Line Lock falls within Title 21 of the Code of Federal Regulations (CFR) 880.5210, Intravascular catheter securement device. An Intravascular catheter securement device is a Class I type device exempt from the premarket notification [510(k)] requirements of the Act, subject to the limitations to the exemption found in 21 CFR 880.9.

However, we have not previously seen the following technological features in an Intravascular catheter securement device: solid colored braided tubing to contain an intravascular catheter; the tubing is sutured to the skin with the catheter inside; and the braided tubing elongates and narrows with movement of the catheter. We believe that the Spinoza Universal Line Lock exceeds the limitations to the exemption in 21 CFR 880.9(b) because it introduces a different fundamental scientific technology to an Intravascular catheter securement device. Therefore, you will need to submit a 510(k) and receive the Food and Drug Administration's (FDA's) clearance prior to marketing this device in the United States. You can not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act.

Please be advised that the practice of securing intravascular catheters with sutures directly exposes the healthcare worker to the risk of needlestick injury from the suture needle and such concerns will have to be addressed in the 510(k). The Occupational Safety and Health Administration's (OSHA's) bloodborne pathogens standard (29 CFR 1910.1030) requires that employers of workers with occupational exposure to blood or other potentially

infectious materials annually consider and implement appropriate, available, and effective safer medical devices designed to eliminate or minimize that exposure [See 29 CFR 1910.1030(c)(1)(iv)(B)]. Engineering controls that reduce the potential for needlesticks by eliminating the need to suture medical catheters in place are one option for healthcare employers to consider. As part of their annual review of methods to reduce needlesticks, employers must review options for securing medical catheters and consider appropriate engineering and work practice controls. Please refer to Standard Interpretations 01/23/2003 - Evaluation of sutureless catheter securement devices to prevent needlestick hazards at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=24428&p_text_version=FALSE.

Please be advised that Title 21 Code of Federal Regulations, Part 807, Subparts A-D, requires all establishments, whether foreign or domestic, that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into or distribution in the U.S. to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 240-276-0132.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents my best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. My response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

If you have any questions regarding this letter, please contact Mr. Anthony Watson, Chief, General Hospital Devices Branch, at (240) 276-3707 or for general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph. D.
Deputy Director for Engineering
and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health